TAB 3

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

Official Contact

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JUL 23 2009

Classification Reference 21 CFR 868.5440

Product Code CAW – Portable Oxygen Generator

Common/Usual Name Portable Oxygen Generator

Proprietary Name Respironics Omni 5 Total O2 Delivery System

Predicate Device(s) Chad Therapeutics Total O2 Delivery System (K013472/K971889)

Reason for submission Modified design.

Substantial Equivalence

The modified device has the following similarities to the previously cleared predicate device:

- ❑ Same intended use.
- ❑ Same operating principle.
- ❑ Same technology.
- ❑ Same manufacturing process.

Design verification tests were performed on the Respironics Omni 5 Total O2 Delivery System as a result of the risk analysis and product requirements. All tests were verified to meet the required acceptance criteria. Respironics has determined that the modifications have no impact on the safety and effectiveness of the device. In summary, the device described in this submission is substantially equivalent to the predicate devices.

The modified device complies with the applicable standards referenced in the Guidance for FDA Reviewers and Industry "Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices," May 2005.

Predicate Device Equivalence:

Substantial equivalence is claimed to the Total O_2 Delivery System, cleared for commercial distribution per K013472.

Device Description

The Omni 5 Total O_2 Delivery System addresses several needs of patients and homecare providers. The Total O_2 Delivery System has been designed to reduce the need for bulk storage and transport of liquid oxygen as well as the storage and transport of high-pressure oxygen tanks. The Omni 5 Total O_2 Delivery System is comprised of conventional pressure adsorption technology which supplies low pressure oxygen to a nasal cannula and/or an integral pressure intensifier which compresses a small portion of the gas to pressures up to 2015 psig in an oxygen gas cylinder for ambulatory use.

The Omni 5 Total O_2 Delivery System has a unique cylinder fill mechanism, which allows it to be easily and safely connected to the patient's Total O_2 oxygen cylinder. The unique cylinder fill mechanism ensures that Total O_2 oxygen cylinders can only be filled through the unique fill port with the Total O_2 Delivery System.

The original Total O_2 Delivery System allowed for continuous oxygen flows and settings from 0 – 3 liters per minute, the modified Total O_2 Delivery System (Omni 5 Total O_2 Delivery System) allows for continuous oxygen flows and settings from 0 – 5 liters per minute. Additionally, the Omni 5 Total O_2 Delivery System incorporates an automatic cylinder filling restart feature, should the oxygen purity fall below acceptable limits (cylinder filling stopped), then recover above the acceptable limits (cylinder filling restarted).

Indications for Use:

The Omni-5 Total O_2 Delivery System is intended to supply low-pressure supplemental oxygen for the treatment of Respiratory Diseases in children through adults in the home, health care facility or hospital and to supply pressurized oxygen to fill oxygen cylinders for patient's ambulatory use.

Intended Use:

The oxygen supplied by the Omni 5 Total O2 Delivery System is supplemental and is not considered to be life supporting and not intended to be used with air or any life support applications or in the presence of flammable anesthetics. Geriatric, pediatric or other patients unable to communicate discomfort may require additional monitoring as with the case with oxygen concentrators currently in use. The device is not sold sterile or intended to be sterilized.

Comparison of Technological Characteristics:

The Omni 5 Total O_2 Delivery System has the same technological characteristics as the predicate device.

The hardware portions of the device are identical except for the following:

- The continuous oxygen outlet flow meter has changed from 0 – 3 liters per minute to 0 – 5 liters per minute (Modification #1 in the submittal).

The software was modified to include:

- An automatic cylinder filling restart feature, should the oxygen purity fall below acceptable limits (cylinder filling stopped), then recover above the acceptable limits (cylinder filling restarted) (Modification #2 in the submittal).

Summary of Testing:

Performance, mechanical, electrical, electromagnetic compatibility, environmental testing and software verification and validation were conducted to demonstrate that the Omni 5 Total O_2 Delivery System would perform as intended.

Conclusions:

Based on the above, we concluded that the Omni 5 Total O_2 Delivery System is substantially equivalent to the Total O_2 Delivery System and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Zita A. Yurko
Director of Regulatory Affairs
Respironics, Incorporated
Sleep & Home Respiratory Group
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668

JUL 23 2009

Re: K091028
Trade/Device Name: Respironics Omni 5 Total O2 Delivery System
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: June 19, 2009
Received: June 22, 2009

Dear Ms. Yurko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091028

Device Name: Respironics Omni 5 Total O2 Delivery System

Indications for Use:

The Omni-5 Total O_2 Delivery System is intended to supply low-pressure supplemental oxygen for the treatment of Respiratory Diseases in children through adults in the home, health care facility or hospital and to supply pressurized oxygen to fill oxygen cylinders for patient's ambulatory use.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultz

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091028